IBUPROFEN- ibuprofen tablet
Granules India Limited

Ibuprofen Tablets, USP 200 mg

Drug Facts

ACTIVE INGREDIENT (in each tablet/caplet)

Ibuprofen 200 mg (NSAID) *

nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/ fever reducer

USES

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
- temporarily reduces fever

WARNINGS

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning

This product contains an NSAID, which may cause severe stomach bleeding.

The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

DO NOT USE

- if you have ever had an allergic reaction to Ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

ASK A DOCTOR BEFORE USE IF

- you have problems or serious side effects from taking pain relievers or fever reducers
- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor’s care for any serious condition
- taking any other drug

WHEN USING THIS PRODUCT

- take with food or milk if stomach upset occurs

STOP USE AND ASK A DOCTOR IF

- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
- chest pain

- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

IF PREGNANT OR BREAST FEEDING,

ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

DIRECTIONS

- **do not take more than directed**
- **the smallest effective dose should be used**

adults and children 12 years and older	• take 1 caplet every 4 to 6 hours while symptoms persist • if pain or fever does not respond to 1 caplet, 2 caplets may be used • do not exceed 6 caplets in 24 hours, unless directed by a doctor
children under 12 years	• ask a doctor

Other Information

- store at 20-25°C (68-77°F)[See USP Controlled Room Temperature]
- avoid high humidity and excessive heat above 40°C (104°F)

INACTIVE INGREDIENTS

colloidal silicon dioxide, iron oxide red, maize starch, poly ethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

QUESTIONS OR COMMENTS?

Call **1-877-770-3183:**
weekdays 9:00 AM to 4:30 PM EST

Manufactured By:
Granules India Limited
Hyderabad – 500 043, India
MADE IN INDIA

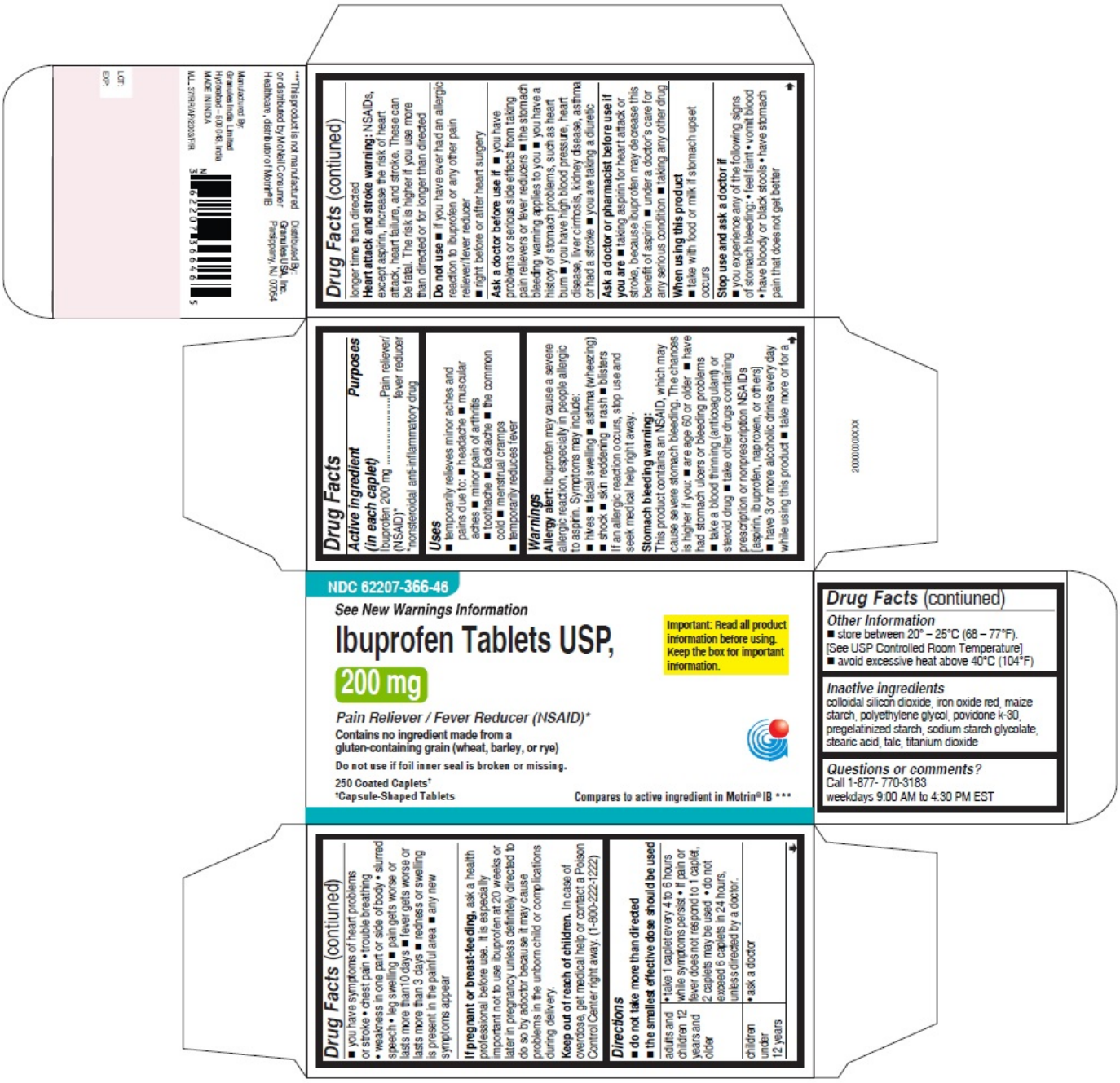
M.L.No: 37/RR/AP/2003/F/R

Distributed By:
Granules USA, Inc.
Parsippany, NJ 07054

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC# 62207-366-46

See New Warnings Information



IBUPROFEN TABLETS USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)*

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

Do not use if foil inner seal is broken or missing.

250 Coated Caplets †

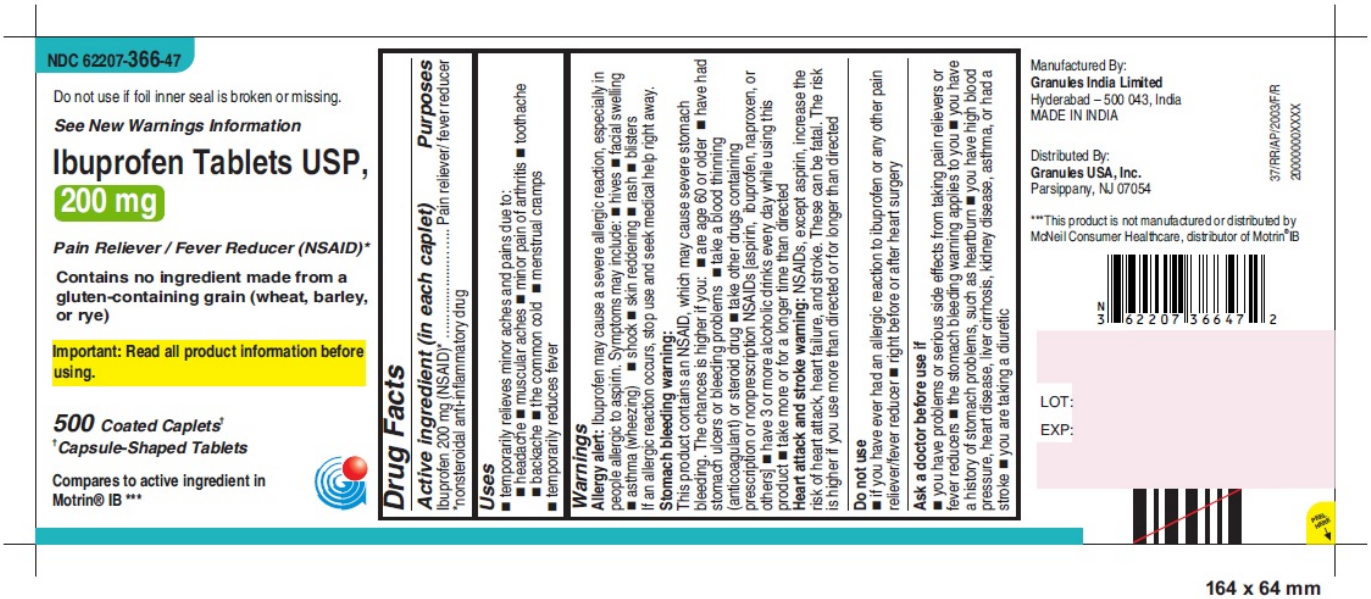
†Capsule-Shaped Tablets

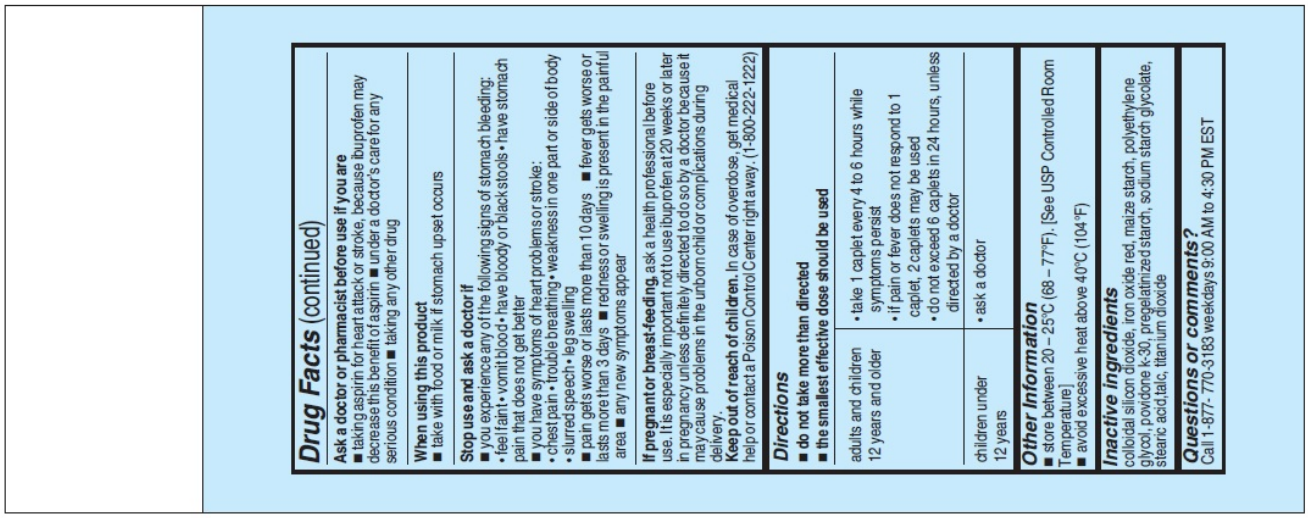
Important: Read all product information before using.

Do not use if the foil inner seal is broken or missing

NDC# 62207-366-47

Do not use if the foil inner seal is broken or missing
See New Warnings Information





IBUPROFEN TABLETS USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)*

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

Do not use if foil inner seal is broken or missing.

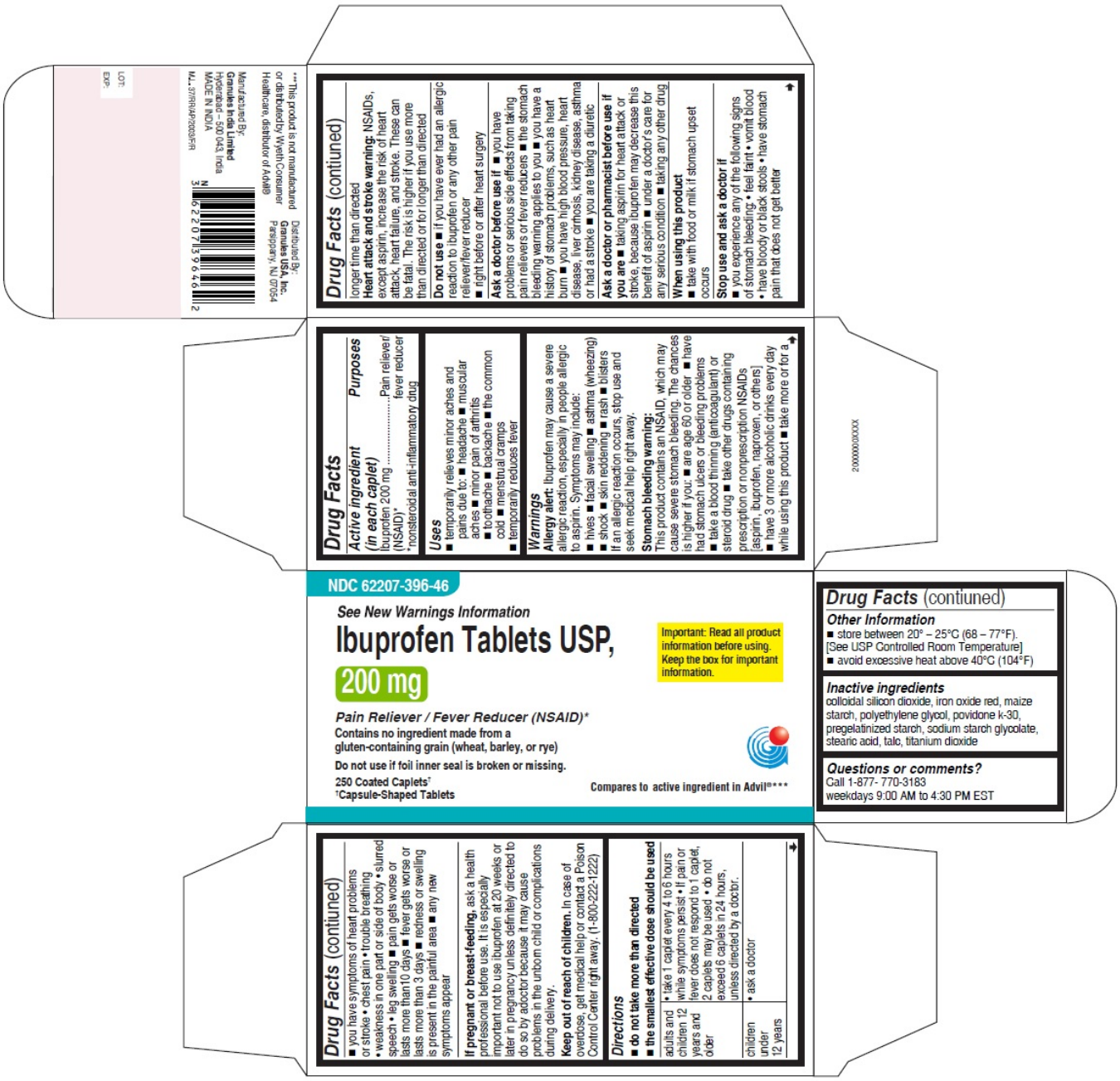
500 Coated Caplets†

†Capsule-Shaped Tablets

Important: Read all product information before using.

NDC# 62207-396-46

See New Warnings Information



IBUPROFEN TABLETS USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)*

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

Do not use if foil inner seal is broken or missing.

250 Coated Caplets†

†Capsule-Shaped Tablets

Important: Read all product information before using.

NDC# 62207-396-46

Do not use if the foil inner seal is broken or missing

See New Warnings Information

Front Side

NDC 62207-396-46

Do not use if foil inner seal is broken or missing.

See New Warnings Information

Ibuprofen Tablets USP, 200 mg

*Pain Reliever / Fever Reducer (NSAID)**

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

Important: Read all product information before using.

***250** Coated Caplets†*

†Capsule-Shaped Tablets

Compares to active ingredient in Advil®***

Drug Facts

Active ingredient Purposes (in each caplet)

Ibuprofen 200 mg ... Pain reliever/ (NSAID)* fever reducer

*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to: ■ headache ■ muscular aches ■ minor pain of arthritis ■ toothache ■ backache ■ the common cold ■ menstrual cramps
- temporarily reduces fever

Warnings

Drug Facts (continued)

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives ■ facial swelling
- asthma (wheezing)
- shock ■ skin reddening
- rash ■ blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chances is higher if you: ■ are age 60 or older ■ have had

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Parsippany, NJ 07054

37/RR/AP/2003/F/R
20000000XXXX

N 3 62207 39646 2

LOT:

EXP:

PEEL HERE

120 x 42 mm

1st Layer Adhesive Side

Drug Facts (continued)

stomach ulcers or bleeding problems ■ take a blood thinning(anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others] ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed

Do not use ■ if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer ■ right before or after heart surgery

Ask a doctor before use if ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ the stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma or had a stroke ■ you are taking a diuretic

Ask a doctor or pharmacist before use if you are ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin ■ under a doctor's care for any serious condition ■ taking any other drug

When using this product ■ take with food or milk if stomach upset occurs

Stop use and ask a doctor if ■ you experience any of the following signs of stomach bleeding: • feel faint • vomit blood • have bloody or black stools • have stomach pain that does not get better ■ you have symptoms of heart problems or stroke: • chest pain • trouble breathing • weakness in one part or side of body • slurred speech • leg swelling ■ pain gets worse or lasts more than10 days ■ fever gets worse or lasts more

2nd Layer

Drug Facts (continued)

than 3 days ■ redness or swelling is present in the painful area ■ any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

■ do not take more than directed
■ the smallest effective dose should be used

adults and children 12 years and older	• take 1 caplet every 4 to 6 hours while symptoms persist • If pain or fever does not respond to 1 caplet, 2 caplets may be used • do not exceed 6 caplets in 24 hours, unless directed by a doctor.
children under 12 years	• ask a doctor

Other Information

■ store between 20 – 25°C (68 – 77°F). [See USP Controlled Room Temperature]
■ avoid excessive heat above 40°C (104°F)

Inactive ingredients

colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid,talc, titanium dioxide

Questions or comments?

Call 1-877-770-3183
weekdays 9:00 AM to 4:30 PM EST

***This product is not manufactured or distributed by Wyeth Consumer Healthcare,distributor of Advil®

IBUPROFEN TABLETS USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)*

Contains no ingredient made from a
gluten-containing grain (wheat, barley, or rye)

Do not use if foil inner seal is broken or missing.

500 Coated Caplets†

†Capsule-Shaped Tablets

Important: Read all product information before using.

IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62207-365
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

Product Characteristics			
Color	red (Reddish Brown)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-365-51	10 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
2	NDC:62207-365-41	24 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
3	NDC:62207-365-42	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
4	NDC:62207-365-43	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
5	NDC:62207-365-46	250 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
6	NDC:62207-365-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
7	NDC:62207-365-48	750 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
8	NDC:62207-365-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	01/01/2011	

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62207-366
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	red (Reddish Brown)	**Score**	no score
Shape	OVAL ((Capsule shaped tablet))	**Size**	14mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-366-51	10 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
2	NDC:62207-366-41	24 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
3	NDC:62207-366-42	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
4	NDC:62207-366-43	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
5	NDC:62207-366-46	250 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
6	NDC:62207-366-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
7	NDC:62207-366-48	750 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
8	NDC:62207-366-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	01/01/2011	

IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62207-396
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	red (Reddish Brown)	**Score**	no score
Shape	OVAL ((Capsule shaped tablet))	**Size**	14mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-396-51	10 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
2	NDC:62207-396-41	24 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
3	NDC:62207-396-42	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
4	NDC:62207-396-43	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
5	NDC:62207-396-46	250 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
6	NDC:62207-396-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
7	NDC:62207-396-48	750 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
8	NDC:62207-396-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	08/13/2019	

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62207-395
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

Product Characteristics

Color	red (Reddish Brown)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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2	NDC:62207-395-41	24 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
3	NDC:62207-395-42	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
4	NDC:62207-395-43	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
5	NDC:62207-395-46	250 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
6	NDC:62207-395-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
7	NDC:62207-395-48	750 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	
8	NDC:62207-395-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	08/13/2019	

Labeler - Granules India Limited (915000087)

Registrant - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(62207-365, 62207-366, 62207-395, 62207-396)

Establishment

Name	Address	ID/FEI	Business Operations
GRANULES LIFE SCIENCES PRIVATE LIMITED		644776835	analysis(62207-365, 62207-366, 62207-395, 62207-396) , manufacture(62207-365, 62207-366, 62207-395, 62207-396) , pack(62207-365, 62207-366, 62207-395, 62207-396) , label(62207-365, 62207-366, 62207-395, 62207-396)

Revised: 8/2024 Granules India Limited